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October 17, 2018



Cheryl Davis R.N., B.S.N.
Supervising Nurse Consultant
Facility Licensing and Investigations Section
Connecticut Department of Public Health
410 Capitol Avenue
PO Box 340308
Hartford CT 06134-0308

Dear Ms. Davis,

Enclosed please find a Plan of Correction in response to violations noted on the unannounced visit to Middlesex Hospital on September 17, 2018 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health.

We appreciate the opportunity to respond to the findings of the investigation. Please contact me with any further questions or needs at (860) 358-6151.

Sincerely,

Claire M. Davis

Claire Davis RN, BSN, MHA, CPHQ FNAHQ
Director of Quality

Enclosure

CORRECTIVE ACTION PLAN

September 17, 2018



STATE FINDINGS/STATE CODE	STATE COMMENTS	FACILITY ACTIONS/RECOMMENDATIONS	FACILITY FOLLOW-UP/RESULTS
The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1) and/or (2) and/or (3) and/or (4) and/or (i) General (6).	<p>1. Based on a review of hospital documentation, hospital committee meeting minutes, e-mail communications, interviews and policies, the hospital failed to regain a state of control in the Clean Room, where sterile products are compounded, after a small water leak was identified. Subsequent to the water leak and before proper sanitation of the room, staff compounded 37 medications that were administered to twenty (20) patients. The finding includes:</p> <p>a. Review of facility documentation dated 7/23/18 identified that during a heavy rainstorm on 7/17/18, water penetrated the exhaust system of the biological safety cabinet (BSC) located in the Pharmacy Clean Room which is utilized to compound chemotherapy. Facility documentation noted that 37 medications were compounded using the LAFW, located in the same room as the BSC during the period of 7/17/18 at 11:00 PM through 7:00 AM on 7/18/18 and administered to Patient #1-20 on 7/17/18.</p> <p>Interview with Pharmacy Technician (PT) #1 on 9/17/18 at 11:10 AM indicated that on 7/17/18 at</p>	<p>Director of Pharmacy or designee will, by November 1, 2018:</p> <ul style="list-style-type: none"> Educate all pharmacy staff via e-mail blast regarding the procedure for immediately communicating any water leak in the Controlled Sterile Compounding Environment, which must include dialing ext. 55 and calling a "Dr. Flood" as well as verbal notification of Pharmacy Director or Supervisor to describe the issue and seek direction as to how to proceed with compounding. Educate all Pharmacy staff regarding the procedure for completing a triple clean of the Controlled Sterile Compounding Environment after any future breaches. Specifically, education must include: completion of two rounds of cleaning with a germicidal detergent followed by a third round with a sporidical; and the necessity to document date and time of breach, subsequent cleaning process and beyond use date (BUD) changes if applicable." Post signage directly exterior to anteroom of the Controlled Sterile Compounding Environment with instructions for staff of the above 	<p>Director of Pharmacy or designee will perform a weekly audit of at least four staff members, for three months (November, December, and January)</p> <p>10/26/18 C.D. at email the facility</p> <p>Director of Pharmacy responsible for file</p> <p>(CAB)</p>

	<p>approximately 8:00 PM, she observed a small amount of water on the floor of the Clean Room in front of the entry door next to the BSC. PT#1 stated she wiped up the water and notified the charge pharmacist (Pharmacist #1). PT#1 stated that the Pharmacist told her she should clean the room like she normally does, since this was not a good thing and should take major steps to clean. PT#1 stated she cleaned the room utilizing bleach, alcohol, Cavicide wipes, and alcohol again. Review of the cleaning log dated 7/17/18 failed to identify that PT#1 cleaned the room. The cleaning log reflected that a three time clean was completed on 7/18/18 by another pharmacy technician.</p> <p>Interview with Pharmacist #1 on 9/17/18 at 8:50 AM indicated that when she was notified of the issue on the evening of 7/17/18 by PT#1, she asked PT#1 to check for further leaks and when informed that there were none, asked PT#1 to clean the room as she normally does. Pharmacist #1 indicated that the other pharmacist on duty (Pharmacist #2) texted the Operations Director to notify him of the issue at that time.</p> <p>Interview with the Operations Director on 9/17/18 at 11:30 AM indicated that he was notified of the water leak on</p>	actions.	
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STATE FINDINGS/STATE CODE	STATE COMMENTS	FACILITY ACTIONS RECOMMENDATIONS	FACILITY FOLLOW-UP/RESULTS
	<p>7/17/18; however, he misunderstood the text and assumed the water leak was in the "new clean room" that was under construction and had been leaking earlier in the day.</p> <p>Interview with the Director of the Pharmacy on 9/17/18 at 8:50 AM and 12:15 PM respectively stated she was notified in the morning of 7/18/18 that PT#1 observed water on the BSC and on the floor beneath the cabinet (on 7/17/18) and notified the charge pharmacist. The Director stated the area was cleaned, however, she was not notified of the incident and compounding was not suspended until she was notified in the morning.</p> <p>The Director stated she was informed that a three-time clean was completed by PT#1 on 7/17/18 but during her discussion with PT#1, the Technician revealed that the products utilized to disinfect the cleanroom after the water leak failed to include a sporicidal. The Director identified she directed only low risk medications be compounded with a one-hour beyond use date (BUD) effective 7/18/18.</p> <p>Review of facility documentation identified that weekly environmental samples of the clean room were obtained during the period of 11/17 through</p>	<ul style="list-style-type: none"> Please note: Samples were obtained during the period of 7/17/18 (day of leak) through 9/17/18 (Day of DPH Survey). 	

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	<p>9/17/18 and revealed no growth.</p> <p>Review of the policy entitled, Sanitation of the Controlled Sterile Compounding Environment, stated that the LAFW and BSC are most intimate to the exposure of critical sites and require disinfection most frequently. Three-time cleaning of controlled environments include the use of two germicidal (alcohol and CaviCide), and a sporidical (Peridox) and may be performed when the following conditions occur, in part; first use and testing of a new facility, after maintenance work, after action levels are identified, and/or at the discretion of the Pharmacy Manager. The policy directed that the cleaning must be documented.</p>		

“The Hospital’s development and implementation of this corrective action plan does not constitute an admission of any fact or violation of law, or a statement that any Hospital policy was not adequate or properly implemented. This corrective action plan has been prepared and will be implemented to comply with regulatory requirements and to further the Hospital’s objective of continually improving patient care.”